510(k) SUMMARY OF SUBSTANTIAL EQUIVALENCE

Proprietary Name:	GORE BIOABSORBABLE MESH
Common Name:	Bioabsorbable Mesh
Classification Name:	Mesh, surgical, polymeric
Device Classification:	Class II
Product Classification and Code:	878.3300, OWT, OWZ, OXC
Classification Panel:	General and Plastic Surgery Devices
Establishment Registration Number:	3003910212
Contact Person:	Michael J. Titus Regulatory Affairs Medical Products Division W. L. Gore & Associates, Inc. 301 Airport Road Elkton, Maryland 21922-1408 Telephone: (410) 506-8316 Facsimile: (410) 506-8221 E-mail: *mtitus@wlgore.com*

Performance Standards

Performance standards do not currently exist for these devices. None established under Section 514.

Device Description

The GORE BIOABSORBABLE MESH is used to reinforce soft tissue during the phases of wound healing by filling or bridging soft-tissue void spaces or defects. The GORE BIOABSORBABLE MESH elicits a physiological tissue response, which fills the defect with native tissue and gradually absorbs the device.

GORE® BIOABSORBABLE MESH is comprised of a microporous structure of synthetic bioabsorbable poly (67% glycolide: 33% trimethylene carbonate by weight) (PGA: TMC) copolymer fiber. This is the same material used in the predicate device (GORE DRAPEABLE ST Regenerative Membrane, K013346, cleared December 19, 2001 and SEAMGUARD, K030782 cleared April 21, 2003).

As packaged, the GORE BIOABSORBABLE MESH is a tailorable, bioabsorbable material intended to be a temporary bridge of defects until the absorptive nature of the device stimulates the body to fill the defect with native tissue. The device is available in sheets and preformed, three-dimensional shapes. The GORE BIOABSORBABLE MESH is provided STERILE for single use only.

Due to the absorptive nature of the GORE BIOABSORBABLE MESH, an overlay patch should be used in corrections requiring high strength (e.g., groin hernia repair)

Indication for Use

The GORE BIOABSORBABLE MESH is intended for use in the reinforcement of soft tissue. Examples of applications where the GORE BIOABSORBABLE MESH may be used include, but are not limited to:

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Hernia repair (inguinal, femoral, umbilical, abdominal, diaphragmatic, incisional, epigastric, gastroesophageal, hiatal, intermuscular).

Muscle flap reinforcement

Perforated tissue repair

General tissue reconstruction's (periosteum, thoracic wall, reinforcement of the bladder wall, suture line reinforcement, tissue deficit, etc.)

In W. L. Gore & Associates, Inc.'s opinion, the GORE BIOABSORBABLE MESH is believed to be substantially equivalent to the following predicate devices currently in interstate commerce with respect to comparable features, materials of construction and intended use.

- SEAMGUARD Bioabsorbable Staple Line Reinforcement Material (W. L. Gore & Associates, Inc., Flagstaff, AZ) – K030782
- GORE DRAPEABLE ST Regenerative Membrane (W.L. Gore & Associates, Inc., Flagstaff, AZ) – K013346
- Vicryl (Ethicon Inc., Somerville, NJ) – K810428
- DePuy Restore® Orthobiologic Soft Tissue Implant (DePuy, Inc., Warsaw, IN) – K001738
- FortaGen (Organogenesis Inc., Canton, MA) – K021105

Summary of Studies

W. L. Gore & Associates, Inc. performed device integrity testing to support that the GORE BIOABSORBABLE MESH is equivalent to the predicate devices. All device integrity test results for the GORE BIOABSORBABLE MESH met specified requirements.

Conclusion (Statement of Equivalence)

Through data and information presented, numerous similarities support a determination of substantial equivalence, and therefore market clearance of the W. L. Gore & Associates, Inc. GORE BIOABSORBABLE MESH through this 510(k) Premarket Notification.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

W.L. Gore & Associates, Inc.
Medical Products Division
% Mr. Brandon Hansen, Regulatory Affairs
3450 West Kiltie Lane
Flagstaff, Arizona 86002-0500

JUL - 2 2012

Re: K033671
Trade/Device Name: GORE Bioabsorbable Mesh
Regulation Number: 878.3300
Regulation Name: Surgical Mesh
Regulatory Class: II
Product Code: OWT, OWZ, OXC
Dated: November 21, 2003
Received: November 24, 2003

Dear Mr. Hansen:

This letter corrects our substantially equivalent letter of December 31, 2003.

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other

requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Mark N. Melkerson
Director
Division of Surgical, Orthopedic
and Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K033671

Device Name: GORE® Bioabsorbable Mesh

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Prescription Use ___X___ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

David Krause for MM

(Division Sign-Off)
Division of Surgical, Orthopedic,
and Restorative Devices

510(k) Number K033671